

105TH CONGRESS  
2D SESSION

# H. R. 3938

To permit the approval and administration of drugs and devices to patients  
who are terminally ill.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 21, 1998

Mr. SHAW (for himself, Mr. CHRISTENSEN, Mr. RAMSTAD, Mrs. JOHNSON of Connecticut, Mr. COBURN, Mr. ROMERO-BARCELÓ, Mr. HAYWORTH, Mr. NEAL of Massachusetts, Mr. BUNNING, Mr. BURTON of Indiana, and Mr. HILLIARD) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To permit the approval and administration of drugs and  
devices to patients who are terminally ill.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Terminally Ill Access  
5       to Treatment Act of 1998”.

6       **SEC. 2. DRUGS AND DEVICES FOR TERMINALLY ILL.**

7       (a) APPROVAL.—The Secretary of Health and  
8       Human Services shall approve, for purposes of treating  
9       the terminally ill only, drugs and devices which have not

1 received final approval from the Food and Drug Adminis-  
2 tration and which have not been shown to be unsafe.

3 (b) ADMINISTRATION.—It is not illegal for a health  
4 care practitioner to administer a drug or device approved  
5 under subsection (a) to a terminally ill patient if the prac-  
6 titioner—

7 (1) has given the patient sufficient notice that  
8 the drug or device has not received final approval  
9 from the Food and Drug Administration and should  
10 be considered experimental; and

11 (2) has received from such patient or the pa-  
12 tient's legal representative written approval to ad-  
13 minister such drug or device.

14 (c) UNSAFE DRUG OR DEVICE.—If a health care  
15 practitioner administers, in accordance with subsection  
16 (b), a drug or device approved under subsection (a) and  
17 determines the drug is unsafe and has caused acute harm  
18 to the practitioner's terminally ill patient, the practitioner  
19 shall cease the administration of the drug or device and  
20 shall report to the Secretary of Health and Human Serv-  
21 ices the practitioner's findings of acute harm.

22 (d) NOTICE.—The Secretary of Health and Human  
23 Services shall give timely public notice of—

24 (1) the benefits derived from a drug or device  
25 approved under subsection (a); and

1           (2) any harm caused by a drug or device ap-  
2       proved under subsection (a).

3       (e) DEFINITIONS.—For purposes of this section—

4           (1) the term “terminally ill” means an individ-  
5       ual who has been certified by a physician as having  
6       an illness or physical condition which can reasonably  
7       be expected to result in death in 24 months or less  
8       after the date of certification; and

9           (2) the term “physician” has the same meaning  
10      as is given that term by section 1861(r)(1) of the  
11      Social Security Act (42 U.S.C 1395x(r)(1)).

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